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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,797	LANGLOIS ET AL.	
	Examiner	Art Unit	
	NELSON YANG	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,12,15,16,19,27,29 and 31-50* is/are pending in the application.

4a) Of the above claim(s) *41-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12,15,16,19,27,29 and 31-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 3, 12, 15, 16, 19, 29, 31, is acknowledged and has been entered.

2. Applicant's cancellation of claims 6-11, 13-14, 17-18, 20-26, 28, and 30 is acknowledged and has been entered.

3. 1-5, 12, 15, 16, 19, 27, 29, 31-50 are pending. Claims 41-50 have been withdrawn.

4. Claims 1-5, 12, 15, 16, 19, 27, 29, 31-40 are currently under examination.

Claim Rejections - 35 USC § 112

5. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, while the specification provides support for the wetted wall sample preparer comprising a super serpentine reactor. While applicant do teach a mixing means that is a super serpentine reactor, there is not indication that this is part of the wetted wall sample preparer.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-4, 12, 27, 29, 31-35, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles et al. [US 6,576,459] in view of Casey et al. [US 2002/0187470] and in view of Irving et al. [US 6,468,330].

With respect to claim 1, Miles et al. teach a sample preparation and analysis device comprising an aerosol collector (column 4, lines 26-28), a filtering device sensitive to density and size differences between particles (column 4, lines 30-35), and mixing the particles with antibody coated beads using an ultrasonic mixer (sample preparation means) (column 4, lines 40-45) for analysis by a detector (flow cytometer, column 4, lines 63-65). Miles et al. further teach a flow cytometer for analysis of the antibody coated beads (column 4, lines 26-28), which would be capable of functioning as a multiplex immunoassay or PCR detector. Miles et al. fail to teach that the use of optically encoded microbeads imbedded with precise ratios of red and orange fluorescent dyes yielding an array of beads, each with a unique spectral address and coated with capture antibodies specific for a given antigen, and also fails to teach a wetted wall sample preparer for preparing a sample of said selected potential bioagent particles connected to said collector.

Casey et al., however, teach optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256), which would make multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256), which can be measured using flow cytometers (para. 0269). Casey et al. further teach that the reporter molecules or haptens may be conjugated by means of a hapten-recognizing intermediary such as antibodies (para. 0065).

Irving et al. further teach aerosol concentrator assembly comprising a two stage system of concentric components to remove large interfering particles and retain small particles for collection and analysis, where a large outer cyclone is used to separate particles and an inner bank of mini-cyclones is used to capture and concentrate particles, wherein particle-laden gas is pulled through the at least one cyclone chambers by a blower so that the particles are separated from the gas by centrifugal force and collected by the liquid supplied to the at least one cyclone chambers (column 3, lines 5-30). Irving et al. further teach that this system is extremely flexible and adaptable for a wide range of possible applications that can be integrated with detector technologies (column 4, lines 7-20). Furthermore, the device is a small and efficient means to separate, capture and concentrate bioparticles from the air for detection (column 2, lines 45-48).

Therefore, it would have been obvious to one of ordinary skill art at the time of the invention to have used optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence in the apparatus of Miles et al., as suggested by Casey et al. as the beads of Miles et al., in order allow for a greater number of labels, which would allow for multiplexed assays that would allow for a greater number of analytes to be detected. It would have further been obvious to one of ordinary skill in the art at the time of the invention to use the aerosol concentrator of Irving et al. comprising a cyclone concentrator in the device of Miles et al., in order to utilize a small and efficient means to separate, capture and concentrate bioparticles from the air for detection.

8. With respect to claim 2, Miles et al. teach a sample preparation and analysis device comprising an aerosol collector (column 4, lines 26-28).

9. With respect to claims 3-4, Miles et al. teach a filtering device sensitive to density and size differences between particles, wherein large particles and dense particles will be transferred to waste (column 4, lines 30-35).

10. With respect to claim 5, the cyclone collector taught by Irving comprises a two stage system of concentric components to remove large interfering particles and retain small particles for collection and analysis, where a large outer cyclone is used to separate particles and an inner bank of mini-cyclones is used to capture and concentrate particles, wherein particle-laden gas is pulled through the at least one cyclone chambers by a blower so that the particles are separated from the gas by centrifugal force and collected by the liquid supplied to the at least one cyclone chambers (column 3, lines 5-30).

11. With respect to claim 12, Miles et al. teach an ultrasonic fractionation device (lysing means, column 4, lines 30-32, 55-65).

12. With respect to claims 15, 16, the cyclone collector taught by Irving may include a fluid collection port as well as a secondary injection port (column 10, lines 28-45), which would be capable of sequential injection as well as flow injection, and would therefore read upon the claims.

13. With respect to claim 27, Miles et al. teach 1-10 μm sized polystyrene beads (column 3, lines 28-31).

14. With respect to claim 29, both Miles et al. and Casey et al. teach the use of flow cytometers as discussed above. Although Miles et al. and Casey et al. fail to specifically teach lasers with wavelengths for read and green, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only

routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, it would have been obvious to one in the art at the time of the invention to have used lasers with wavelengths for read and green through normal optimization procedures to optimize the excitation of the labels encoding the beads.

15. With respect to claims 31, 32, Miles et al. teach immunoassay and PCR detectors (see 46, 77 of the figure).

16. With respect to claim 33-37, Miles et al. teach a second set of electrodes in amplification/concentration components for PCR amplification and detection of DNA. Miles then teach a flow cytometer for analysis of the antibody coated beads (column 4, lines 26-28), which would also be capable of functioning as a multiplex immunoassay or PCR detector for analyzing optically encoded microbeads, such as those of Casey et al. Miles et al. also teach the use of Taqman assays (column 4, lines 60-65) which are quantitative PCR assays and which would require a PCR detector, and that the fluorescent signal is detected in real-time (column 4, lines 64-65).

17. With respect to claims 38, 39, Miles teach a PCR passage section for treating particles comprising reagents, ultrasonic mixers, PCR detectors, DEP concentration/purification components, and thin film heators for PCR preparation (column 4, lines 23-25, 38-46, 55-60, figure).

18. With respect to claim 40, Miles et al. teach ultrasonic mixers and DFP bead concentrator for mixing and holding in place antibody-coated beads (column 4, lines 40-48).

19. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles et al. [US 6,576,459] in view of Casey et al. [US 2002/0187470] and in view of Irving et al. [US

6,468,330], as applied to claim 1 above, and further in view of Colston, Jr. et al. [US 2003/0032172].

With respect to claim 19, the Miles et al. teach an ultrasound mixer as discussed above, but fail to teach a super serpentine reactor.

Colston, Jr. et al., however, teach that mixers such as super serpentine reactors may be used to combine the sample and the PCR reagents. Therefore, one of ordinary skill in the art at the time of the invention, when presented with these two references, would have found it obvious substitute the ultrasound mixer of Miles et al. with the super serpentine reactor of Colston, Jr. et al. to perform the mixing of the reagents and PCR sample during the PCR preparation stage in the invention of Miles et al., as these are equivalent structures known in the art.

20. Claims 1-5, 29, 32, 33, 35-37 are rejected are rejected under 35 U.S.C. 103(a) as being unpatentable over Daugherty et al. [US 2004/0028561] in view of Casey et al. [US 2002/0187470] and Irving et al. [US 6,469,330].

With respect to claim 1, Daugherty et al. teach a bio-hazard collection and testing system comprising a collection subsystem for collecting particles resident in the air surrounding objects (para. 0008), a filtration subsystem for separating the bio-hazardous sized particles from collected particles for testing, a sampling subsystem for preparing a sample containing the bio-hazardous particles, and an analysis subsystem for detecting and determining the composition of the biohazardous particles in the analysis sample (para. 0007). Daugherty et al. fail to teach a detector comoprising a flow cytometer for use with optically encoded microbeads imbedded with precise ratios of red and orange fluorescent dyes yielding an array of beads, each with a unique

spectral address and coated with capture antibodies specific for a given antigen, and also fails to teach an aerosol collector that is a wetted wall cyclone collector that concentrates said potential bioagent particles in a liquid.

Casey et al., however, teach optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256), which would make multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256) as well as a flow cytometer comprising a laser unit (para. 0270) for performing the multiplexed assays (para. 0269).

Irving et al. further teach aerosol concentrator assembly comprising a two stage system of concentric components to remove large interfering particles and retain small particles for collection and analysis, where a large outer cyclone is used to separate particles and an inner bank of mini-cyclones is used to capture and concentrate particles, wherein particle-laden gas is pulled through the at least one cyclone chambers by a blower so that the particles are separated from the gas by centrifugal force and collected by the liquid supplied to the at least one cyclone chambers (column 3, lines 5-30). Irving et al. further teach that this system is extremely flexible and adaptable for a wide range of possible applications that can be integrated with detector technologies (column 4, lines 7-20). Furthermore, the device is a small and efficient means to separate, capture and concentrate bioparticles from the air for detection (column 2, lines 45-48).

Therefore, it would have been obvious in the apparatus of Daugherty et al. to have used a flow cytometer and optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence, as suggested by Casey et al. as the analysis subsystem and for labeling the analytes of Daugherty et al., in order to allow for

multiplexed assays that would allow for a greater number of analytes to be detected. It would have further been obvious to one of ordinary skill in the art at the time of the invention to use the aerosol concentrator of Irving et al. comprising a cyclone concentrator in the device of Daugherty et al., in order to utilize a small and efficient means to separate, capture and concentrate bioparticles from the air for detection.

21. With respect to claim 2, Daugherty et al. teach a concentrating the particles using a conventional aerosol concentrator (para. 0032).

22. With respect to claims 3, Daugherty et al. teach a filtration subsystem (separator means) for separating the bio-hazardous sized particles from collected particles for testing (para.007).

23. With respect to claims 4, Daugherty et al. teach a filtration subsystem (separator means) for separating the bio-hazardous sized particles (separation based on predetermined size) from collected particles for testing (para. 0007).

24. With respect to claim 5, Daugherty et al. teach a filtering means wherein unfiltered air is first captured by a set of pitot tubes, pre-filtered, and transported to the triggering and sampling subsystems (para.007). As previously described, prefilter allows the large particles to pass into main air flow (bypass air flow), while retaining the smaller particles which are captured by the prefilter at inlet flow (FIG. 7B) and passed to receiving probe, where air and particles exit the receiving probe as minor flow (product air flow).

25. With respect to claim 29, Casey et al. teach the use of flow cytometers as discussed above. Although Casey et al. fail to specifically teach lasers with wavelengths for read and green, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*,

105 USPQ 233. Therefore, it would have been obvious to one in the art at the time of the invention to have used lasers with wavelengths for read and green through normal optimization procedures to optimize the excitation of the labels encoding the beads.

26. With respect to claims 32, 33, 35, 37, the sampling subsystem prepares a liquid sample suitable for conventional bioassay test strip analysis, conventional polymerase chain reaction (PCR) analysis (nucleic acid assays sample) (para. 0032)., whereas Casey et al. provides detection systems for multiplexed PCR analysis (para. 0187, 0188).

27. With respect to claim 36, the sampling subsystem prepares a liquid sample suitable for conventional bioassay test strip analysis, conventional polymerase chain reaction (PCR) analysis (nucleic acid assays sample) (para. 0032). Daugherty et al. further teach that the analysis subsystem can execute in real-time (para. 0011).

28. With respect to claim 37, the subsystem of Daugherty et al. is capable of amplifying DNA (para. 0037).

29. With respect to claims 38, 39, Daugherty et al. teach transport subsystem (para. 0008) for moving objections past a collection subsystem (para. 0008) and an analysis subsystem for performing PCR or DNA analysis on liquid medium based samples (para. 0037). Casey et al. further disclose that for PCR analysis, reagents (para. 0065), mixers (para. 0259), and detection means (para. 0011) are necessary. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the analysis subsystem of Daugherty et al. to comprise a means for adding a sample, adding PCR reagents, mixers and detection means. Daugherty et al. further teach a decontamination subsystem for neutralizing bio-hazordous particles (para. 0007).

Response to Arguments

30. Applicant's arguments with respect to claims 1-5, 12, 15, 16, 19, 27, 29, 31-40 have been considered but are moot in view of the new ground(s) of rejection. The Office notes, however, that the rejections are substantially identical, as the reason finality was withdrawn was due to Irving et al. [US 6,469,330] being incorrectly labeled as Lawless [US 4,923,491] and to also address the 112, 1st paragraph. Therefore, applicant may wish to continue with the filing of the appeal brief in response to this office action.

31. Applicant's arguments in the appeal brief have also been addressed, in order to further expedite prosecution.

32. In response to applicant's arguments that the Miles reference does not show "autonomous monitoring apparatus for monitoring for bioagents wherein the air may contain potential bioagent particles, the recitation automated monitoring apparatus has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

33. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. In particular, with respect to applicant's arguments that the prior art fails to teach a "collector for gathering

said air being monitored, said collector separating selected potential bioagent particles from said air," the Office notes that, as discussed in the prior office action and above, the prior art teach an aerosol collector (column 4, lines 26-28), which collects particles from air, and a filtering device sensitive to density and size differences between particles (column 4, lines 30-35).

34. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In particular, with respect to applicant's arguments that the Miles reference fails to teach a wetted wall sample preparer for preparing a sample of said selected potential bioagent particles connected to said collector, the Office notes that this was acknowledged in the prior office action, and further notes that the secondary reference, Irving et al., teaches this limitation, and also further teach that this system is extremely flexible and adaptable for a wide range of possible applications that can be integrated with detector technologies (column 4, lines 7-20). Furthermore, the device is a small and efficient means to separate, capture and concentrate bioparticles from the air for detection (column 2, lines 45-48).

35. With respect to applicant's argument that the Miles reference fails to teach a detector for detecting said bioagents in a sample or a flow cytometer, the Office notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In

particular, Miles teach a flow cytometer (column 4, lines 45-53, 60-65) for detecting the presence of pathogens on beads (column 4, lines 40-50)

36. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Irving et al. teach that the cyclone collector allows for a small and efficient means to separate, capture and concentrate bioparticles from the air for detection (column 2, lines 45-48), while using the beads of Casey et al. would allow for a greater number of labels, which would allow for multiplexed assays that would allow for a greater number of analytes to be detected.

37. With respect to applicant's arguments that the combination of Miles, Casey and Irving et al. fail to teach the limitations, "autonomous monitoring apparatus for monitoring air for bioagents wherein the air may contain potential bioagent particles," or "a collector for gathering said air being monitored, said collector separating selected potential bioagent particles from said air," or "a wetted wall sample preparer for preparing a sample of said selected potential bioagent particles, said wetted wall sample preparer operatively connected to said collector for collecting and preparing said sample from said air gathered by said collector wherein said wetted wall sample preparer includes a wetted wall cyclone collector that concentrates said selected potential

bioagent particles in a liquid and a unit for adding optically encoded microbeads imbedded with precise ratios of red and orange fluorescent dyes yielding an array of beads having a unique spectral address and each bead coated with capture antibodies specific for a given antigen to said liquid and said selected potential bioagent particles," or "a detector for detecting said bioagents in said sample, said detector operatively connected to said wetted wall sample preparer wherein said detector utilizes said optically encoded microbeads," or "wherein said detector includes a flow cytometer for analyzing said optically encoded microbeads that are imbedded with precise ratios of red and orange fluorescent dyes yielding an array of beads having a unique spectral address and each bead coated with capture antibodies specific for a given antigen with a laser unit for individually interrogating said optically encoded microbeads and detecting said bioagents," or "said collector includes a separator for separating said potential bioagent particles from said other particles," or "means for lysis of said spores," or "polystyrene beads," or "said laser unit includes a red laser that classifies said microbeads and a green laser that quantifies said microbeads," or "said sample preparation means includes optically encoded microbeads and bead suspension/mixer means for suspending said microbeads for a predetermined time period," the Office disagrees.

38. In particular, the limitation of "autonomous monitoring apparatus for monitoring for bioagents wherein the air may contain potential bioagent particles, the recitation automated monitoring apparatus has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural

limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

39. Miles et al. teach a sample preparation and analysis device comprising an aerosol collector (column 4, lines 26-28) which corresponds to a collector for gathering said air being monitored, said collector separating selected potential bioagent particles from said air,", and mixing the particles with antibody coated beads using an ultrasonic mixer (sample preparation means) (column 4, lines 40-45) for analysis by a detector (flow cytometer, column 4, lines 63-65), which corresponds to the limitations of "a detector for detecting said bioagents in said sample, said detector operatively connected to said wetted wall sample preparer wherein said detector utilizes said optically encoded microbeads," Miles et al. further teach a flow cytometer for analysis of the antibody coated beads (column 4, lines 26-28), which would be capable of functioning as a multiplex immunoassay or PCR detector.

40. Casey et al. teach optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256), which would make multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256) and which corresponds to the limitation of "optically encoded microbeads that are imbedded with precise ratios of red and orange fluorescent dyes yielding an array of beads having a unique spectral address and each bead coated with capture antibodies specific for a given antigen with a laser unit for individually interrogating said optically encoded microbeads and detecting said bioagents,". Casey et al. further teach that the reporter molecules or haptens may be conjugated by means of a hapten-recognizing intermediary such as antibodies (para. 0065).

41. Irving et al. further teach aerosol concentrator assembly comprising a two stage system of concentric components to remove large interfering particles and retain small particles for collection and analysis, where a large outer cyclone is used to separate particles and an inner bank of mini-cyclones is used to capture and concentrate particles, wherein particle-laden gas is pulled through the at least one cyclone chambers by a blower so that the particles are separated from the gas by centrifugal force and collected by the liquid supplied to the at least one cyclone chambers (column 3, lines 5-30). This corresponds to the limitation of "a wetted wall sample preparer for preparing a sample of said selected potential bioagent particles, said wetted wall sample preparer operatively connected to said collector for collecting and preparing said sample from said air gathered by said collector wherein said wetted wall sample preparer includes a wetted wall cyclone collector that concentrates said selected potential bioagent particles in a liquid"

42. In response to applicant's arguments that the Daugherty reference does not show "autonomous monitoring apparatus for monitoring for bioagents wherein the air may contain potential bioagent particles, the recitation automated monitoring apparatus has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

43. With respect to applicant's arguments that the prior art fails to teach a "collector for gathering said air being monitored, said collector separating selected potential bioagent particles from said air," the Office notes that as discussed above and in the previous office action, Daugherty et al. teach a bio-hazard collection and testing system comprising a collection subsystem for collecting particles resident in the air surrounding objects (para. 0008), a filtration subsystem for separating the bio-hazardous sized particles from collected particles for testing, a sampling subsystem for preparing a sample containing the bio-hazardous particles, and an analysis subsystem for determining the composition of the biohazardous particles in the analysis sample (para. 0007).

44. With respect to applicant's argument that the Daugherty reference fails to teach a detector for detecting said bioagents in a sample or a flow cytometer, the Office notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In particular, the prior art teach an analysis subsystem for detecting and determining the composition of the biohazardous particles in the analysis sample (para. 0007).

45. With respect to applicant's argument that the Miles reference fails to teach a detector for detecting said bioagents in a sample or a flow cytometer, the Office notes that this limitation is taught by the Casey reference.

46. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching,

suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Irving et al. teach that the cyclone collector allows for a small and efficient means to separate, capture and concentrate bioparticles from the air for detection (column 2, lines 45-48), while using the beads of Casey et al. would allow for a greater number of labels, which would allow for multiplexed assays that would allow for a greater number of analytes to be detected.

47. With respect to applicant's arguments that the combination of Daugherty, Casey and Irving et al. fail to teach the limitations, "autonomous monitoring apparatus for monitoring air for bioagents wherein the air may contain potential bioagent particles," or "a collector for gathering said air being monitored, said collector separating selected potential bioagent particles from said air," or "a wetted wall sample preparer for preparing a sample of said selected potential bioagent particles, said wetted wall sample preparer operatively connected to said collector for collecting and preparing said sample from said air gathered by said collector wherein said wetted wall sample preparer includes a wetted wall cyclone collector that concentrates said selected potential bioagent particles in a liquid and a unit for adding optically encoded microbeads imbedded with precise ratios of red and orange fluorescent dyes yielding an array of beads having a unique spectral address and each bead coated with capture antibodies specific for a given antigen to said liquid and said selected potential bioagent particles," or "a detector for detecting said bioagents in said sample, said detector operatively connected to said wetted wall

sample preparer wherein said detector utilizes said optically encoded microbeads," or "wherein said detector includes a flow cytometer for analyzing said optically encoded microbeads that are imbedded with precise ratios of red and orange fluorescent dyes yielding an array of beads having a unique spectral address and each bead coated with capture antibodies specific for a given antigen with a laser unit for individually interrogating said optically encoded microbeads and detecting said bioagents," or "said collector includes a separator for separating said potential bioagent particles from said other particles," or "means for lysis of said spores," or "polystyrene beads," or "said laser unit includes a red laser that classifies said microbeads and a green laser that quantifies said microbeads," or "said sample preparation means includes optically encoded microbeads and bead suspension/mixer means for suspending said microbeads for a predetermined time period," the Office disagrees.

48. In particular, Daugherty et al. teach a bio-hazard collection and testing system comprising a collection subsystem for collecting particles resident in the air surrounding objects (para. 0008), a filtration subsystem for separating the bio-hazardous sized particles from collected particles for testing, a sampling subsystem for preparing a sample containing the bio-hazardous particles, and an analysis subsystem for detecting and determining the composition of the biohazardous particles in the analysis sample (para. 0007). Daugherty et al. fail to teach a detector comoprising a flow cytometer for use with optically encoded microbeads imbedded with precise ratios of red and orange fluorescent dyes yielding an array of beads, each with a unique spectral address and coated with capture antibodies specific for a given antigen, and also fails to teach an aerosol collector that is a wetted wall cyclone collector that concentrates said potential bioagent particles in a liquid.

49. Casey et al., teach optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256), which would make multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256) as well as a flow cytometer comprising a laser unit (para. 0270) for performing the multiplexed assays (para. 0269).

50. Irving et al. further teach aerosol concentrator assembly comprising a two stage system of concentric components to remove large interfering particles and retain small particles for collection and analysis, where a large outer cyclone is used to separate particles and an inner bank of mini-cyclones is used to capture and concentrate particles, wherein particle-laden gas is pulled through the at least one cyclone chambers by a blower so that the particles are separated from the gas by centrifugal force and collected by the liquid supplied to the at least one cyclone chambers (column 3, lines 5-30).

Conclusion

51. No claims are allowed.

52. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

53. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Patent Examiner
Art Unit 1641